NOVARTIS

Patient information leaflet
Read this package leaflet carefully before taking this medicine.
This medicine has been prescribed for you personally. Do not pass it on to anyone else. It may harm them even if their symptoms are the same as yours.
Keep this leaflet. You may want to read it again later.

Femara®

What Femara is and what it is used for
Femara contains the active substance letrozole and is known as an aromatase inhibitor. It reduces the effect of the sex hormones (oestrogens) in your body. Oestrogens can promote the growth of certain types of breast cancer.

Femara is used to treat breast cancer in women after the menopause either as an additional treatment in early-stage breast cancer following surgery – where Femara is used immediately or after 5 years of treatment with tamoxifen – or in advanced breast cancer.
Femara may only be used if prescribed by your doctor.

Do not take Femara
Do not take Femara:
- If you have previously had an unusual or allergic reaction to letrozole or any of the other ingredients of this medicine. If you think you may be allergic, ask your doctor for advice.
- If you still have periods.
- If you are pregnant or breast-feeding.

Children and adolescents: Femara is not suitable for use in children and adolescents.

Warnings and precautions
In some cases tiredness and dizziness have been reported during treatment with Femara. If you experience either of these effects, do not drive, use machines or carry out any other activity that requires an increased level of attention.
Your bone mineral content may decrease if you take Femara for a prolonged period. Your doctor will therefore regularly monitor this and may prescribe you a medicine to prevent or treat osteoporosis.
Before you take Femara, your doctor may check your hormone levels to ensure that you have gone through the menopause (i.e. you no longer have periods).
Interactions with other medicines: Femara should not be taken with tamoxifen, other anti-oestrogens or medicines containing oestrogen (e.g. hormone replacement therapy). These medicines may reduce the effect of Femara.
Letrozole may cause tendon inflammation or tendon injury (see "Possible side effects"). If there are any signs of tendon pain or swelling, rest the painful area and contact your doctor.
Femara should not be used with some other medicines such as those used to treat infections (fungal infections, e.g. posaconazole, itraconazole, voriconazole and bacterial infections, e.g. antibiotics such as clarithromycin or telithromycin), medicines used to treat tuberculosis such as rifampicin, medicines with St. John's wort extracts used to treat depression and other conditions (also known as *Hypericum perforatum*), medicines used to treat (epileptic) seizures (such as phenytoin, carbamazepine and phenobarbital), medicines used to treat AIDS (HIV) such as ritonavir or cobicistat or medicines used to prevent blood clotting such as clopidogrel.
Tell your doctor or pharmacist if you:
- Suffer from a severe kidney or liver disease.
- Have a history of osteoporosis or bone fractures.
- Suffer from any other illnesses.
- Have any allergies.
- Are taking or externally applying any other medicines (including non-prescription medicines).

Pregnancy and breast-feeding
Femara is only intended for use after the menopause. If you are pregnant or breast-feeding, do not take Femara under any circumstances.
However, your doctor must discuss the necessity of adequate contraception with you if you are currently going through the menopause or have recently gone through the menopause as you may still be able to become pregnant during this period. If your menopause status is unclear, your doctor will perform a hormone test before starting treatment.

How to use Femara
The recommended dose is one film-coated tablet (2.5 mg) daily. The tablet should be swallowed with a liquid. It can be taken with or without food.
Your doctor will decide how long you will be treated with Femara.
If you forget to take Femara, take it as soon as you remember. If you realise you forgot to take Femara and it is almost time for the next dose, do not take the forgotten dose. Do not take a double dose.
If you accidentally take more film-coated tablets than prescribed, tell your doctor or pharmacist.
Do not change the prescribed dosage yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor or pharmacist.

Possible side effects
The following side effects may occur when taking Femara. Many of them (e.g. hot flushes, hair loss, vaginal bleeding) are caused by the consequences of stopping hormone production in your body.
Side effects may occur with a certain frequency:
Very common (affects more than 1 in 10 patients)
Common (affects 1-10 in 100 patients)
Uncommon (affects 1-10 in 1,000 patients)
Rare (affects 1-10 in 10,000 patients)
Very rare (affects fewer than 1 in 10,000 patients)
Not known (frequency cannot be estimated based on the available data)

Very common: Hot flushes; joint pain; increased cholesterol in the blood; increased sweating; fatigue (including tiredness/drowsiness, general weakness, malaise/feeling unwell).
Common: Loss of appetite; increased appetite; weight gain; headache; dizziness; feeling that you or your surroundings are spinning or moving (vertigo); depression; high blood pressure; nausea; vomiting; digestion disorders; constipation; diarrhoea; hair loss; vaginal bleeding; dry skin; abdominal pain; back pain, heart palpitations; chest pain; rash with redness (erythematous rash); bumpy, blotchy rash (maculopapular rash); silvery, flaky rash (psoriasiform rash); rash with blisters (vesicular rash); muscle pain, bone pain; joint inflammation (arthritis); osteoporosis; bone fractures; swelling/puffiness of mainly the arms or legs due to accumulation of body fluid (peripheral oedema); blockage of a blood vessel by a blood clot.
Uncommon: Urinary tract infection; anxiety; nervousness; irritability; drowsiness; sleeplessness; memory problems; abnormal sensation in the skin (dysaesthesia); abnormal discomfort in the skin with no apparent cause such as a tingling sensation in the arms and legs (paraesthesia); numbness or reduced sensitivity in touch and pressure affecting the skin (hypoaesthesia); pain or burning sensation in the hands or wrists (carpal tunnel syndrome); problems with taste; eye irritation, blurred vision; clouding of eye lenses; increased heart rate; heart failure; heart conditions due to decreased blood flow (including angina pectoris (new or worsening angina, angina requiring surgery) and heart attack); stroke (including temporary decreased blood flow to the brain); low blood pressure; painful surface inflammation along a vein; shortness of breath; cough; dry mouth; inflammation of the mucous membrane in the mouth; dry mucous membranes; rash; itching; increased frequency of urination; vaginal discharge; vaginal dryness; breast pain; fever; thirst; swelling/puffiness due to accumulation of body fluid (generalised oedema); decreased number of white blood cells; weight loss; change in liver values; increased bilirubin levels (dark urine); jaundice (yellowing of eyes and/or skin); tendon inflammation (tendonitis).
Rare: Blood clots in the blood vessels of the lungs; blood clots in the arteries, tendon rupture (tear).
Very rare: Yellowing of eyes and/or skin, nausea, loss of appetite, dark urine (signs of hepatitis).
Frequency not known: Severe allergic reactions (anaphylactic reactions); swelling primarily of the face, lips, tongue and/or throat (angioedema); life-threatening, severe rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (signs of a skin disease known as toxic epidermal necrolysis); rash, red skin, blistering of the lips, eyes or mouth, skin peeling (erythema multiforme); trigger finger (a condition in which your finger or thumb remains in a bent position).
Tell your doctor or pharmacist if the side effects do not disappear during the course of treatment or cause you problems or if you experience any side effects that are not listed above.

Further information
Protect from moisture and do not store above 30°C.
Keep out of the reach of children.
Do not use after the expiry date (= EXP) printed on the pack.
Your doctor or pharmacist will be able to give you more information. They have access to the full prescribing information.

What Femara contains
1 film-coated tablet contains 2.5 mg letrozole and other ingredients.
Excipients: Colloidal anhydrous silica, microcristalline cellulose, lactose monohydrate, magnesium stearate, maize starch, sodium starch glycollate, hydroxypropyl methylcellulose, polyethylene glycol 8000, talc, titanium dioxide (E 171), iron oxide yellow (E 172).
Information might differ in some countries.

Availability/pack sizes
Available only in pharmacies with a doctor's prescription.
2.5 mg film-coated tablets: 30 and 100.
Not all Pack sizes may be available in the countries.

Manufacturer
Novartis Pharma Stein AG, Switzerland for Novartis Pharma AG, Lichtstrasse 35 Basel, Switzerland
This package leaflet was last reviewed by the Swiss Agency for Therapeutic Products (Swissmedic) in August 2020.

® = registered trademark

Novartis Pharma AG, Basle, Switzerl and

This is a medicament
- A medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Council of Arab Health Ministers Union of Arab Pharmacists